# BLOOD TREATMENT SYSTEM PROVIDING PULSATILE FLOW AND METHOD OF USE

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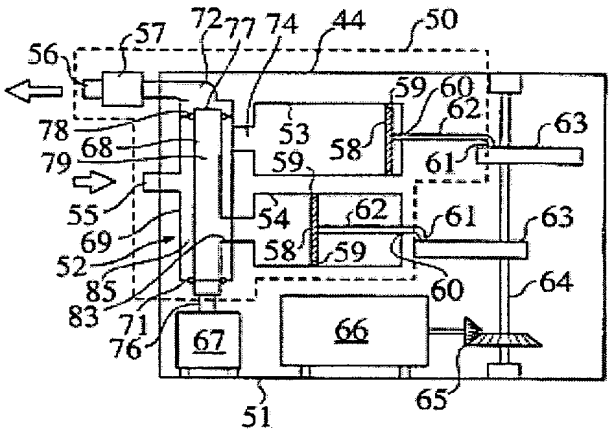
Abstract of **WO0108719**

Apparatus and methods are described for use in mass transfer blood treatment systems, such as hemodialysis, hemofiltration or blood oxygenation units, that include a pump having an inlet port, an outlet port, first and second reservoirs, a valve that selectively interconnects the reservoirs to the inlet and outlet ports. A controller synchronizes operation of the valve and first and second reservoirs to provide simultaneous inlet and outlet displacement flow patterns which are independent of each other. The apparatus further may be implemented in a networked configuration to permit key parameters regarding a patient's treatment session with the blood treatment unit to be uploaded to a remote health care provider for prompt evaluation.



# BLOOD TREATMENT SYSTEM PROVIDING PULSATILE FLOW AND METHOD OF USE

Description of **WO0108719**

BLOOD TREATMENT SYSTEMS PROVIDING
PULSATILE FLOW AND METHODS OF USE
Field Of The Invention
The present invention relates to apparatus and methods for providing pulsatile flow in mass transfer units. such as hemodialysis and cardiopulmonary bypass machines, and collecting and reporting data generated during operation of such units.

Background Of The Invention
Hemodialysis systems are known forcleansing blood of metabolites in patients having renal deficiency. Such systems typically involve flowing blood in contact with a first surface of a membrane or bundle and flowing a dialysate in contact with an opposing surface of the membrane or bundle. so that certain proteins and metabolites migrate from the blood across the membrane into the dialysate.

Where equal pressures are used on either side of the membrane, the mass transfer effect is referred toas"hemodialysis"; where the blood side pressure exceeds the dialysate pressure, the mass transfer effect is referred toas"hemofiltration."
It has long been known that it may be desirable to create pulsatile flow on one or both sides of the dialyzer membrane to disrupt laminar flow along the membrane. and thus enhance mass transfer. For example. U. S. Patent No. to Bellhouse describes a mass transfer unithaving a corrugated mass transfer membrane that creates turbulence in the blood and dialysate flows adjacent to the membrane. U. S.

Patent No. to Runge et al. describes a hemodialysis system that employs an external mechanism to cyclically compress a bladder-type chamber to enhance dialysis. U. S. Patent No.4. 492. 531 to Kenji et al. describes a system for use in hemodialysis that uses a standard roller pump. pressure absorbing bladder. and pinchvalve synchronized to the patient's EKG to induce pulse-like flow.

While the need for pulsatile flow has been recognized in the prior art. none of the proposed solutions have gainedwidespread acceptance.Many, such as that described in the aforementionedRunge patent. aremechanically complicated.Others, such as the system described in Kenji et al., may not be capable of developing sufficient pressure fluctuations to provide a beneficial effect.Moreover, the previously known devices are not amenable to low-cost production for disposal after a single-use. Consequently, commercially available hemodialysis units generally use previously known constant volume roller pumps to pump both the dialysate and the patient's blood, and trade reduced mass transfer efficiency for lower cost.

In addition, previously known pulsatile flow systems. such as described in the foregoing Runge and Kenji et al. patents, inherently require that there be little or no forward blood flow while the bladder is recharging with blood. Compared to constant volume pumps, the benefits achieved by previously known pulsatile pumps, in terms of mass transfer efficiency, may be offset by the pulsatile flow pumps providing positive flow for a shorter period of time.

Another drawback associated with previously known dialysis units is the inability of such systems to measure key parameters relevant in assessing the efficiency of a dialysis session, such as the actual rate of blood flow and resistance to flow in the patient'sarteriovenous fistula('AV fistula'). For patients requiring a permanent access site for dialysis. an AV fistula typically is formed by providing an anastomosis of the radial artery to the cephalic vein. Over the course of several months, the venous limb of the fistula dilates and its wallsthicken, permitting repeated insertion of dialysis needles.

When used as the vascular access site for dialysis over a period of years, however, the fistula gradually becomes obstructed, and may interfere with the efficacy of the dialysis treatment. Inparticular, increased resistance to flow in the AV fistula may result in much less blood being filtered during agiven dialysis session than might otherwise be expected based, for example, on roller-pump speed and session duration. This occurs because, in the absence of sufficient forward blood flow. the blood pump of the dialyzer will take up a percentage of the dialyzed blood entering the fistula via the venous needle. thereby recirculating the dialyzed blood and compromising the efficiency of the dialysis session.

Yet another drawback associated with previously known dialysis systems is the inability to compile

information relating to a hemodialysis session in a manner that is useful to the care provider. For example. it is typical in previously known dialysis centers-which may be frequented by hundreds of patients a day-for only a few relevant statistics about each patient's dialysis session, e. g., dialysis time and total blood volumetreated. to be recorded manually on charts. This limited information is then transmitted for review to a care provider. such as a physician at a health maintenance organization("HMO"), days or weeks later. Due to the inability of such previously known dialysis systems to generate and record meaningful data with respect to a patient's dialysis session, the care provider may not detect a problem with a patient's dialysis program until more serious complications arise.

While some previously known systems, such as the di-PROTON system sold by ClinicalComputing, Cincinnati, Ohio and theFinesseg Dialysis Management
System offered by Fresenius Medical Care, Bad Homburg, Germany and Isymed
Gmbh, offer automated machine set-up and data collection for dialysis systems via network connection, these systems are not believed to provide monitoring of key parameters, such as the actual blood flow rate or resistance to flow in the patient's AV fistula. This is so because neither actual blood flow rate nor hemodynamic resistance in the patient's AV fistula are generally obtainable using previously known roller pump-based dialysis machines.

In view of the shortcomings of previously known pulsatile blood flow systems, it would be desirable to provide apparatus and methods for performing mass exchange, such as hemodialysis or cardiopulmonary bypass, that induce systolic-like pressure waves.

It also would be desirable to provide apparatus and methods that enhance mass transfer by disrupting laminar flow within a dialysis/filtration or oxygenation unit.

It further would be desirable to provide apparatus and methods for facilitating measurement of the actual blood flow rate, the hemodynamic resistance of a patient's
AV fistula, and other parameters relevant in assessing the therapeutic effects of a dialysis session.

It still further would be desirable to provide methods and apparatus that enable real-time measurement of parameters relevant to a dialysis session, such as actual blood flow rate or resistance to flow in the AV fistula, volume of blood dialyzed. etc., continuously or at selected points throughout a dialysis session. and which provides for that data to be transmitted to the care provider for review and evaluation.

Summarv Of The Invention
In view of theforegoing, it is an object of this invention to provide apparatus and methods for performing mass exchange, such as hemodialysis or cardiopulmonary bypass, that induce systolic-like pressure waves.

It is another object of this invention to provide apparatus and methods that enhance mass transfer by disrupting laminar flow within the dialysis/filtration or oxygenation unit.

It is a further object of the present invention to provide apparatus and methods for inducing time-varying or pulsatile flow in mass exchange systems that provide positive flow at varying pressure, required for recharging previously known systems.

It is another object of the present invention to provide apparatus and methods for facilitating measurement of the blood flow rate delivered by the pump to the patients, the hemodynamic resistance of a patient's AV fistula, and other parameters relevant in assessing the therapeutic effects of a dialysis session.

It is a still further object of this invention to provide methods and apparatus that enable real-time measurement of parameters relevant to a dialysis session. such as actual blood flow rate, resistance to flow in the AV fistula, volume of blood dialyzed, etc., continuously or at selected points throughout a dialysis session. and which provide for that data to be transmitted to the care provider for review and evaluation.

It is yet another object of the invention to provide methods and apparatus for pumping blood or other biological fluids that enable inlet and outlet flow rates that are independent of each other over a pump cycle.

It is still another object of the invention to provide an apparatus and methods for pumping blood that allow backflow for a portion of the outlet cycle.

These and other objects of the present invention are accomplished by providing a mass exchange system including a pump means providing simultaneous inlet and outlet displacement flow patterns which are

independent of each other. In the context of a dialysis system. the pump of the present invention facilitates measurement of the flow rate and pressure of blood delivered by the pump to the patient, and permits computation of the resistance to blood flow in the patient's AV fistula. Thus, key parameters, relevant in assessing the therapeutic benefit of a dialysis session, may be continuously or intermittently monitored throughout a session.

Detailed information regarding a patient's dialysis session is than stored and transmitted or made available to the patient's care provider for review and evaluation.

In a preferred illustrative embodiment of the present invention, a dialysis system comprises a disposable time-varying pump assembly including first and second non-compliant reservoirs coupled to a valve wherein the valve is operable to cause the first reservoir to fill while the second reservoir is discharged and the first reservoir to discharge while the second reservoir is filled. This assembly. permits blood flow rate, pump outlet pressure. and flow resistance to be readily monitored.

As used herein, the term"non-compliant"is intended to refer to a system that does not experience a substantial change in volume, i. e. less than5% and preferably less than 1% with an increase in pressure expected during a normal pump stroke.Typical pressure excursions are about200-750 mm Hg. The pump assembly is coupled to a reusable drive system and controller that record and store data regarding relevant parameters, such as pump rate, resistance to flow, flow rate, instantaneous pressure and session duration for each dialysis session. The data then may be processed and transmitted over a local area network, a wide area network, or both, to a computer available to a care provider for prompt review and evaluation.

The disposable pump assembly preferably includes an inlet port. an outlet port, first and second fluid reservoirs such as cylinders. and a valve that selectively interconnects the reservoirs to the inlet and outlet ports. Fluid in the cylinders is in direct contact with the piston faces to provide a system that is non-compliant whereby fluid flow can be easily and directly derived for each piston stroke. The pump assembly may be coupled to a drive system and controller that optionally synchronizes operation of the valve and first and second reservoirs. The valve is configured so that when the first reservoir is coupled to discharge through the outlet port, the second reservoir is coupled to fill from the inlet port, and blood is ejected or discharged from the first reservoir while the second reservoir recharges. Conversely, when the first reservoir is coupled to the inlet port. the second cylinder is coupled to the outlet port, and blood is ejected from the second reservoir while the first reservoir recharges or fills.

In a preferred embodiment of the invention, the flow pattern of blood entering the pump assembly and blood exiting the pump assembly may each by time-varying but independent of each other. Further, the flow pattern of the discharge side of the pump assembly may include a portion where the blood flow is reversed in direction, i. e. where there is backflow of blood into the pump assembly.

The pump assembly and drive system of the present invention preferably are configured to be used to retrofit pumps used in previously known dialysis. hemofiltration, and oxygenation systems, such as roller pumps, to reduce the capital cost of upgrading previously owned blood treatment systems.

Methods of using the apparatus of the present invention to enhance mass transfer in hemodialysis, hemofiltration and oxygenation units, and to store and transmit relevant data concerning a patient's treatment session also are provided.

Brief Description Of TheDrawings

Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawings and the following detailed description of the preferredembodiments, in which:
FIG.1 is a schematic view of an illustrative hemodialysis center using the apparatus of, and configured in accordance with the methods of. the present invention;
FIG. 2 is a schematic view of a first embodiment of the dialysis system of the present invention;
FIG. 3 is a schematic view of an alternative embodiment of the dialysis system of the present invention ;
FIG. 4 is a schematic view of a hemodialysis system employing a pump constructed in accordance with the principles of the present invention;
FIG. 5 is a side sectional view of the pump assembly and drive system of the present invention;
FIG. 6 is a partial exploded perspective view of the pump assembly of FIG. 5;
FIGS. 7A-7C are schematic side and plan sectional views of the pump assembly of FIG. 5 showing ejection of fluid from the upper cylinder;
FIGS.8A-8C are schematic side and plan sectional views of the pump assembly of FIG. 5 showing ejection of fluid from the lower cylinder;
FIG. 9 is an exploded perspective view of an alternative embodiment of a valve constructed in accordance with the present invention :

FIGS.I OA andI OB are sectional views of the valve of FIG. 9 in the first and second positions; and FIG. 11 is a graphic illustration of flow profile as a function of valve position and piston displacement.

Detailed Description Of The Invention

The present invention relates generally to apparatus and methods for inducing time-varying or pulsatile flow in a mass transfer system. such as a hemodialysis, hemofiltration or blood oxygenation system, and for collecting. storing and transmitting data during use of such systems. In accordance with a preferred embodiment of the present invention, a disposable pump assembly and drive system are provided that enable key parameters, such as blood flow rate, pressure and resistance to flow in the patient's AV fistula. to be accurately computed and/or monitored during a dialysis session. These data may be stored and/or processed for later transmission to, and review and evaluation by, a care provider.

In a preferred embodiment of the pump assembly of the present invention, a fluctuating pressure wave-form is induced in blood flowing through the treatment unit, where the pressure wave-form mimics systolic flow. The pressure fluctuations are expected to disrupt laminar flow fields within the dialysis or oxygenation unit, thereby enhancing mass transfer. In addition, it is expected that the systolic-like flow characteristics of blood returned to the patient will cyclically stretch the endothelium, thereby further enhancing mass transfer. as described. for example, in Champsaur, et al.,"Flow-induced Releaseof Endothelium-derived Relaxing Factor During Pulsatile
Bypass: Experimental Study in the FetalLamb,"J. Thoracic and Card.Sure..

114 (5):739-745 (1997). Accordingly, the overall time that the patient must be connected to the treatment system is expected to be significantly reduced.

In a preferred embodiment of the invention, the apparatus includes a disposable pump assembly comprising a valve and two positive displacement constant-filling cylinders, and a reusable drive system and controller. The apparatus further includes one or more sensors for monitoring the flow rate and pressure of blood leaving the pump assembly, and for computing resistance to flow encountered at the pump outlet. The controller may be programmed to synchronize operation of the valve with the cylinders, and also optionally may synchronize operation of the system to the patient's heartbeat, for example, using a signal output from a pulse oximeter.

The pump assembly is arranged so that in a first position blood is ejected from the first cylinder while the other cylinder is recharged with blood. and in the second position, the first cylinder is recharged while the second cylinder ejects blood to the dialysis unit.Advantageously, the use of two cylinders makes the pump'constantfilling", although there may be brief pauses or even backflow in the flow pattern of the pump assembly inlet. The pump of the present invention therefore avoids the requirement of substantial intervals such as are required in previously known pulsatile pumps recharge, and during which there is no positive flow through the dialysis or oxygenation unit. In addition, the pump assembly and drive system of the present invention may be readily adapted to retrofitpre-existing blood treatment systems.

Referring to FIG. 1, illustrative clinic 10 having network11 of hemodialysis systems 12 of the present invention is described. Hemodialysis clinic is of the type where patients afflicted with renal disease make, on average, three visits per week to undergo dialysis, and comprises a plurality of booths in which patients may relax and read while undergoing dialysis. Each dialysis system 12 comprises pump13 and controller14. as described in detail hereinafter. Controllers 14 are coupled to server computer 15 via network11, for example, an Ethernet local area network. Each of controllers 14 records and stores data throughout a patient's dialysis session. and in accordance with the methods of the present invention, enables that information to be provided to each patient's health care provider.

Controllers 14 preferably are programmed to compile and upload information for each patient's dialysis session to server computer 15 during or upon completion of each dialysis session. Server computer 15 in turn may be programmed to transfer that information via a dial-up modem connection or dedicated line to server computer 16 of one or more health care providers via public standard telephone network 17.

Communication between server computer 15 and server computer 16 may be either by direct dial connection, or alternatively over a wide area network. such as the Internet.

A system configured as depicted in FIG.1 therefore enables information critical to assessing the efficacy of a dialysis regime to be transmitted and made available to health care providers promptly upon completion of a dialysis session.

Although some previously known systems provide automated data collection and transmission, as described hereinabove, those systems lack the enabling technology of the pump constructed in accordance with the principles of the present invention.

Consequently, those previously known systems are believed to be incapable of providing data on key parameters, such as actual blood flow rate, pressure at the pump outlet or increased flow resistance in the A-V fistula, thatdramatically effect the beneficial effect of a dialysis session.

Referring now to FIG.2. greater detail is provided with respect to dialysis systems 12 of FIG.1. Pump13 comprises positive displacement cylinders 20 coupled to multi-position valve 21 and drive system22. and includes an inlet line23 and return line 24. Pump13 includes sensors. described below, and is controlled by, and provides relevant datato. controller 14.

Controller 14 comprises microprocessor 25 coupled to ROM26. RAM 27,
storage device28, network interface card ("NIC") 29, inputpanel 30 anddisplay 31.

ROM 26 stores the microprocessor firmware. while storage device 28, illustratively a
hard disk drive, stores the programming that operates drive system 22. Storage device 28 also preferably stores programming for monitoring sensors incorporated in pump
13, and for analyzing that sensor data and uploading the relevant information to server computer 15 via NIC 29.

Inputpanel 30, e.g., a touch sensitive screen orkeyboard, enables controller
14 to be selectively programmed to provide the desired treatment parameters, e. g., flow rate, etc., for a dialysis session. Input panel 30 also permits data relevant to a patient, such as the patient's name or patient identifier number, pre-and post-dialysis weight, etc., to be input to the controller for purposes of tracking and transmitting data regarding the dialysis session. Display31 permits information input via inputpanel 30 to be verified, and also permits key parameters relevant to a dialysis session to be displayed, such as the pump flow rate, cumulative dialyzed volume, resistance to flow, temperature, pressure, duration of session, and the patient's name or patient identifier number.

In accordance with one aspect of the present invention, controller 14 may be programmed to analyze and sample data collected during the course of a dialysis session, and process that data in a manner suitable for ready comprehension by the health care provider. For example. the controller 14 may be programmed to process or sample data collected throughout the dialysis session and render that information in graphical form or other forms that facilitate comprehension by the health care provider. In addition, controller 14 also may be programmed to sound an alarm when critical parameters, such as blood flow rate, pressure and flow resistance encountered in the A-V fistula, exceed predetermined limits input via input panel 30.

InFIG. 3, an alternative embodiment of hemodialysis system 12 of FIG.1 is described. Dialysis system 35 is similar to system12 of FIGS.I and 2 and includes pump13 and controller 14. Controller, 14 differs from that of FIG. 2, however, in that storage device 36 is substituted for NIC 29. In this case. controllers 14 are not coupled directly to network11. Instead. removable items of media 37 are inserted into storage device 36 at the beginning of a dialysis session, and then removed upon completion of the session. Data stored on the removable media 37 may then be transferred to a separate computer (not shown) for upload to server computer 15 and dispatch to server computer 16 of the health care provider.

Referring now to FIG. 4. an illustrative hemodialysis or hemofiltration system constructed in accordance with the principles of the present invention is described.

Apparatus 40 includes a mass transfer or mass exchange unit such as dialysis unit 41, dialysate reservoir 42, dialysate pump43. blood pump 44. controller45, and pulse sensor 46. Dialysis unit41, reservoir 42 and pump43 preferably comprise previously known devices, such as manufactured by Fresenius MedicalCare, Bad Homburg,Germany, and are interconnected by suitable tubing 47, as is known in the art.

Dialysis unit 41 includes a membrane or filter bundle defining blood side 41 a and dialysate side41b.

Blood pump 44 is coupled to the patient and blood side 41 a of dialysis unit 41 using suitable biocompatible tubing 48. Tubing 48 includes inlet line 48a and outlet line 48b coupled to the patient's A-V fistula. Blood entering pump 44 from inlet line 48a is directed through blood side41a of dialysis unit41, and returned to the patient's
A-V fistula via outlet line 48b. Controller 45, as described hereinabove, controls operation of pump 44 so that blood returned to the patient has a pressure-wave-formapproximating that of the patient's blood pressure. In a preferred embodiment, controller 45 may in addition comprise previously known pulse oximetry circuitry, and be coupled to pulse sensor 16 (e. g., a pulse oximeter sensor). As is known in the art, tubing 48 in addition may include a metered pump or drip line (nor shown) for infusing a small amountof antithrombogenic drug, such as heparin. into the blood passing through the dialysis unit to

reduce the risk of clotting.

With respect to FIG. 5, blood pump 44 is described in greater detail. Pump 44 comprises disposable pump assembly50 (enclosed within the dotted line) removably coupled to reusable drive system51. Pump assembly 50 includes multi-position valve 52 coupled to cylinders53 and 54. Valve52 includes inlet port55 and outlet port 56 having pressure monitoring port 57 for measuring the pressure at the outlet of the pump 44. Pressure monitoring port 57 may comprise, for example. an elastomercovered window having a pressure transducer in contact therewith. and may be used to generate a signal corresponding to the pressure encountered at the pump outlet. from which resistance in the A-V fistula may be computed.

In a preferred embodiment. each of cylinders53 and54 includes piston 58 having 0-ring59 seated in a groove in the perimeter of the piston. Rods 62 extend through openings 60 at the rear of each cylinder53 and54, and include arms 61 that areslidingly captured in grooves63a of eccentric cams63 (see FIG. 6). Eccentric cams 63 are disposed on axle 64 of drive system51 * so that axle 64 is driven by gearing 65 and motor 66 under the control of controller 14. Alternatively, motor 66 may be coupled directly to axle64. thus omitting gearing 65 and reducing the complexity of the device.

Eccentric cams63 (viewed sideways in FIG. 5) are 180 out of phase, so that when piston53 is at its minimum stroke length (i. e., in the charging position depicted in FIG. 5), cylinder 54 is at its maximum stroke length. In addition, grooves 63a of cams 63 preferably are designed so that pistons 58 and rods 62 have a rapid stroke duringan"ejection"or"discharge phase", followed by a pause at the end of each ejection phase. and then a gradual retraction of the pistons duringa"filling"or "recharge phase", as determined by the shape of groove63a and the eccentricity of the cam. Inlet and outlet flow patterns can thus be controlled by the grooves. It is advantageously possible with this system to provide a certain amount of blood backflow during the outlet portion of each cycle.

Referring now to FIG.11, an exemplary outlet flow is illustrated and described as segments A-F of a sequence of output flow pulses, each of which contains backflow, discharge and dwell phases. The output pulse may contain some or all of these phases and may contain more than one of any phase. The inlet flow is also illustrated in terms of pulses.However, in the preferredembodiement. the inlet or filling flow is as uniform as possible and the pulse is dominated by the charge phase. The pauses in inlet flow are required to accommodate the outlet pulse backflow phase and valve switching time. The length of the various phases i

During segmentB, pistonl continues to be retracted, producing inlet flow (recharge phase). Piston 2 is extended through its entire stroke, producing positive outlet flow (discharge phase).

During segmentC, the valve remains in position 2. Piston 1 completes the charge stroke. completing the recharge phase. Piston 2 is stationary and outlet flow pauses (dwell phase).

At the beginning of segment D. piston 2 is fully extended into the cylinder (100% displacement) and pistonl is fully retracted (0% displacement). During segment D, the valve remains in position 2. connecting cylinder 2 (piston 2) to the pump outlet. Cylinderl, (piston 1) is connected to the pump inlet. Piston 2 is retracted while remaining connected to the pump outlet. This causes the outlet flow to reverse direction (backflow phase). During this segment piston 1 remains stationary and inlet flow pauses.

At the beginning of segment E, the valve is switched back to position1, connecting cylinder 1 (piston 1) to the pump outlet and cylinder 2 (piston 2) to the pump inlet. During segment E, piston 2 continues to be retracted, producing inlet flow (recharge phase). Piston 1 is extended through its entire stroke, producing positive outlet flow (discharge phase).

During segment F, the valve remains in position1. Piston 2 completes the charge stroke, completing the recharge phase. Piston 1 is stationary and outlet flow pauses (dwell phase).

In an alternative embodiment (not shown) the pumps may be digitally controlled linear pumps with the flow patterns being precisely controlled by a microcontroller.

Referring again to FIG.5. drive system 51 also includes valve actuator motor 67 which is coupled to valve body 68 of valve 52. Valve body 68 is rotated within housing 69 of valve 52 in synchrony with operation of pistons 58 of cylinders53 and 54 under the control of controller 14. as describedhereinbelow. Valve actuator motor may comprise, for example. a stepper motor.

With respect to FIG.6, a preferred embodiment is described. in which cylinders53 and 54 and housing 69 of valve 52 may be integrally formed using an injection molding process. In FIG. 6. piece 70 includes one-

half of the cylinders53.

54 and valve housing 69. As will of course be understood. another piece (not shown), which is the mirror-image of piece 70. is bonded (e. g.. byglue. ultrasonicenergy or heat) to piece 70 after pistons58 and valve body 68 are assembled between the halves.

Referring still to FIGS.5 and 6. controller 14 regulates the speed of motor 66 and operation of valve actuator motor 67 so that pistons58 cause blood within the cylinders 53 and 54 to be expelled through outlet port56 with a pressure wave-form that mimics systolic pressures within blood side41 a of dialysis unit 41. Once piston 58 attains its maximum stroke length during the ejection phase. arm 61 of rod 62 slides through a flattened portion of groove63a of cam 63, thereby causing a diastolic-like pause in the blood flow.Simultaneously. rotation of axle 64 causes the rod and piston of the other cylinder to gradually retract during its filling phase, thereby allowing that cylinder to recharge.

Valve 52 includes valve body 68 rotatably disposed within housing 69.

Housing 69 preferably comprises a biocompatiblematerial, and includes inlet port 55, outlet port 56, base 71. plenum 72, sidewall73 and side ports 74 and 75. Inlet port 55 is configured for connection to inlet line 48a. Each of side ports 74 and 75 is coupled to a respective cylinder53 and 54. Sidewall73 has a smooth inner surface, for example, coated withTEFLONg, i. e., polytetrafluoroethylene, for the reasons described hereinbelow.

Valve body 68 includes hub 76 that removably couples to valve actuator motor 67, and upper end 77 that seats in O-ring 78 and opens into plenum 72. Valve body 68 includes longitudinal bore 79 that opens into plenum 72 and side members 80 and 81 having bores 82 and83, respectively, that communicate with longitudinal bore 79.

When valve body 68 is disposed within housing 69, the outermost ends of side members 80 and 81 slide along the inner surface of sidewall73. Side members 80 and 81 arecircumferentially offset from one another so that when bore 82 of side member 80 is aligned with side port74. bore 83 of side member 81 is sealed by the inner surface of sidewall73. Conversely, when bore83 of side member 81 is aligned with side port 75, bore 82 of side member 80 is sealed by the inner surface of sidewall73.

Accordingly, valve body 68 is configured so that blood is ejected from one of cylinders53 and 54, the bore of the side member associated with the other cylinder is sealed, thus causing the blood to exit valve 52 via plenum 72 and outlet port 56.

As will be apparent from inspection of valve 52, blood from inlet line 48a continuously flows through pump inlet port 55 and into annulus 85 defined by the exterior of valve body 68 and the inner surface of sidewall73 of housing 69 (see
FIGS. 5 and 6). Consequently, when one of side members 80 and 81 of valve body 68
is aligned with its respective side port 74 or 75, the other side member is moved clear of the other side port 74 or 75, allowing blood to pass from annulus 85 through that side port into the corresponding cylinder53 or 54. Because one of side ports 74,75 is always in communication with annulus 85 between the valve body and the housing, the design of pump assembly 50 ensures that one of the cylinders recharges with blood while blood is being expelled from the other cylinder.

Referring to FIGS. 7A-7C and 8A-BC, operation of blood pump 44 in accordance with the methods of the present invention is further described. During an initial priming and initialization step, valve body 68 is alternately rotated so each of cylinders 53 and 54 fills with blood from inlet line 48a through inlet port55 and annulus 85. Pulse sensor 46 then may be applied to the patient so that controller45 may operate in synchrony with. or counter pulsation to. the patient's heart rhythm.

During pumping operation, valve body 68 is rotated to a first position by valve actuator motor 67, responsive to controller 45, wherein side member 80 is coupled to cylinder 53 (FIG. 7B), and side member 81 is sealed against the inner surface of sidewall 73. Simultaneously, this movement of valve body 68 causes cylinder 54 to communicate with annulus 85 via side port 75, thereby permitting blood to charge cylinder 54 (FIG. 7C). Motor 66 rotates axle 64 responsive to controller45. causing eccentric cam 63 to push rod 62 of cylinder 53 to expel blood through side port 74, bore 82, longitudinal bore 79 and outlet port 56 to blood side 41 a of dialysis unit 41 (FIG. 7A), while at the same time retracting piston 58 of cylinder 54 to permit that cylinder to recharge with blood.

Upon completion of the ejection phase stroke of piston 58 of cylinder53, arm 61 rides through aflattened portion of groove63a, thereby mimicking a diastolic interval. This portion of the outlet flow pattern may

include a portion where there is a reversal of flow direction of the blood. Controller 45 then causes valve actuator motor 67 to rotate valve body 68 to a second position, shown in FIG. 8A, in which side member 80 is sealed against the inner surface of sidewall73 (FIG. 8B) and side member 81 is coupled to cylinder54 via side port 75 (FIG. 8C). In this position side port 74 of cylinder53 communicates with annulus85. thus causing cylinder53 to recharge. Continued rotation of axle 64 causes piston 58 of cylinder 54 to expel blood from that cylinder, while also retracting piston 58 of cylinder53 to permit re-filling of that cylinder.

Upon completion of the ejection phase stroke of piston 58 of cylinder 54 and the diastolic-like pause. controller 45 again signals valve actuator motor 67 to return valve body 68 to the first position, so that blood is expelled from cylinder53 while cylinder54 recharges with blood. Controller45 thereafter cycles valve body 68 between the first and second positions to alternately expel blood from cylinders 53 and54. respectively. Advantageously. because for pump 44 one cylinder is always being actuated while the other recharges, there is no significant time lag associated with recharging the cylinders, as encountered with previously known pulsatile blood pumps.

In accordance with one aspect of the present invention, displacement of pistons 58 within cylinders 53 and 54 results in a known volume of blood being expelled into the blood side of the dialysis unit. and from there to the patient's AVfistula. In conjunction with pressure monitoring port57 formeasuring the pressure at the outlet of the pump 44 (see FIG. 5), and the fact that the positive displacement nature of blood pump 44 permits accurate calculation of the blood flow rate at the pump outlet, blood pump 44 provides all of the data needed to continuously monitor the resistance to flow encountered during perfusion of dialyzed blood into the patient's AV-fistula. These key parameters then may be stored and transmitted to the health care provider using the network configurations of FIGS. 1-3, thus providing the capability for prompt evaluation of the efficacy of a patient's dialysis session.

Referring now to FIGS. 9 and10A-10B. an alternative embodiment of a valve constructed in accordance with the principles of the present invention is described.

Valve 90 includes valve body 91 disposed for sliding movement within housing 92.

Housing 92 preferably comprises a biocompatible material, and includes base 93, lid 94, sidewall 95, inlet port 96 and side ports 97 and 98. Inlet port 96 is configured for connection to inlet line 48a. Side ports 97 and 98 are coupled to cylinders53 and 54, for example, as part of an integrally molded piece, as described hereinabove with respect to FIG. 6. Sidewall 95 has a smooth inner surface, for example. coated with polytetrafluoroethylene(TEFLoN$).

Valve body 91 includes rod 100 that extends through aperture101 of base93, and spring 102 that biases valve body 91 in direction D. Valve body 91 also includes portion 103 that projects through lid 94 to engage with valve actuator motor 67 (see
FIG. 5). Valve body 91 includes longitudinal blind bore 104 that extends through portion103 to form outlet port105. and side members 106 and 107 having bores 108 and 109. respectively, that communicate with longitudinal bore 104.

When valve body 91 is disposed within housing 92. the outermost ends of side members 106 and 107 slide along the inner surface of sidewall 95. Side members 106 and 107 are spaced apart longitudinally from one another so that when bore 108 of side member 106 is aligned with side port 97, bore 109 of side member 107 is sealed by the inner surface of sidewall 95. Conversely, when bore 109 of side member 107 is aligned with side port 98, bore 108 of side member 97 is sealed by the inner surface of sidewall 95. Accordingly, valve body 91 is configured so that blood is ejected from one of cylinders53, the bore of the side member associated with the other cylinder is sealed, thus causing the blood to exit valve 90 via outlet port 105.

As will be apparent from inspection of valve 90, blood from inlet line 48a continuously flows through pump inlet port 96 and into annulus110 defined by the exterior of valve body 91 and the inner surface of sidewall 95 of housing 92 (see
FIGS.I OA and1 OB). Consequently, when one of side members 106 and 107 of valve body 91 is aligned with its respective side port 97 or 98, the other side member is moved clear of the other side port 97 or 98, allowing blood to pass from annulus110 through that side port into the corresponding cylinder 53 or 54. Because one of side ports 97,98 is always in communication with annulus110 between the valve body and the housing, the one of the cylinders recharges with blood while blood is being expelled from the other cylinder.

Portion103 of valve body 91 preferably is coupled to valve actuator motor 67, such as a stepper motor, through suitable gearing that slides valve body 91 between a first position, wherein cylinder 53 is coupled

to outlet port 105, and a second position, wherein cylinder 54 is coupled to outlet port105. As for the embodiment of FIG. 5, valve actuator motor 67 moves valve body 91 responsive to signals generated by controller 45, and portion 103 may include rack gear111 adapted to be interengaged with a pinion ring of the stepper motor. Alternatively, portion103 may be coupled to valve actuator motor 67 by other suitable means, such as a linear actuator.

Referring to FIGS.I OA and1 OB, operation of blood pump 44 employing valve 90 is described. During an initial priming and initializationstep. valve body 91 is alternately moved so each of cylinders 53 and 54 fills with blood from inlet line 48a through inlet port 96 and annulus110. Valve body 91 then is pulled in direction C by valve actuator motor 67 to a first position wherein side member 106 is coupled to cylinder 53 (FIG.10A). and side member107 is sealed against the inner surface of sidewall 95. In this position. blood from annulus110 communicates with cylinder54.

Controller 45 also causes motor 66 to rotate axle 64, which operates the piston of cylinder53 to expel blood through side port 97 to blood side41a of dialysis unit 11, while simultaneously causing the piston of cylinder 54 to retract.

Upon completion of the stroke of the piston of cylinder53, and after any pause imposed by the shape of the groove of the eccentric cam. controller 45 causes valve actuator motor 67 to rotate valve body 91 to a second position wherein side member 106 is sealed against the inner surface of sidewall 95 and side member 107 is coupled to cylinder 54 (FIG.10B). This movement of valve body 91 also enables annulus110 to communicate with cylinder53 via side port 97. Continued rotation of axle 64 and eccentric cams 63 causes piston58 of cylinder 54 to expel blood through side port 98, bore 104 and outlet port 105 to blood side4 la of dialysis unit41, while causing piston 58 of cylinder53 to retract and draw blood from annulus 110 into cylinder53.

As for valve 52 of FIG. 5, because valve 90 permits one cylinder to be actuated while the other cylinder recharges, there is no time lag associated with recharging the cylinders, as encountered with previously known pulsatile blood pumps.

Further in accordance with the principles of the present invention, blood pump 44 preferably is designed to permit it to be retrofitted to previously known dialysis machines. Applicant expects that the pulsatile flow provided by the constant filling pump of the present invention may significantly reduce dialysis session times by enhancing mass transfer in the dialysis unit and enhancing the release of endothelial factors by cyclically stretching the patient's endothelium. as described hereinabove. In addition, pump 44 of the present invention advantageously may be substituted for roller pump 43 of FIG. 4, thereby further enhancing mass transfer in dialysis unit 41 by providing pulsatile flow on both sides of the system.

Applicant also expects the pump and networkable configuration of the present invention to find application in cardiopulmonary bypass machines ("CPB machines").

Previously known CPB machines also may benefit from disruption of laminar flow around the hollow fiber bundles used in such machines. and the pulsatile flow generated by the pump of the present invention also may provide benefits with respect to stretching the endothelium to enhance release of endothelial factors.

Moreover, a pump constructed in accordance with the principles of the present invention is expected to provide higher flow rates than previously known pulsatile pumps. This advantage is expected to be particularly beneficial in the context of blood oxygenation. because the pump of the present invention will enable the use of smaller oxygenators that require a lower priming volume. In addition. the pump of the present invention may facilitate heat transfer in heat exchanger applications.

While preferred illustrative embodiments of the invention are described above, it will be apparent to one skilled in the art that various changes and modifications may be made therein without departing from the invention. and the appended claims are intended to cover all such changes and modifications that fall within the true spirit and scope of the invention.

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# BLOOD TREATMENT SYSTEM PROVIDING PULSATILE FLOW AND METHOD OF USE

Claims of **WO0108719**

What Is Claimed Is:

1. Apparatus for producing a time-varying flow of a fluid in a medical treatment unit. the apparatus comprising:
first and second reservoirs including first and second pistons for direct fluid contact: and
a valve coupled to the first and second reservoirs wherein said valve is operable to cause said first reservoir to fill while said second reservoir is discharged and said first reservoir to discharge while said second reservoir is filled.

2. The apparatus of claiml wherein said valve includes an inlet port and an outlet port, the valve having a first position wherein the inlet port is coupled to the first reservoir and the outlet port is coupled to the second reservoir. and a second position wherein the outlet port is coupled to the first reservoir and the inlet port is coupled to the second reservoir; and
a controller that causes the valve to move between the first and second positions, the controller causing actuation of the first reservoir when the valve is in the second position and actuation of the second reservoir when the valve is in the first position.

3. The apparatus of claim 2 wherein the valve and the first and second reservoirs form a disposable single-use pump assembly.

4. The apparatus of claim 2 and further comprising a drive system that actuates the pistons of the first and second reservoirs responsive to the controller.

5. The apparatus of claim 1 wherein the valve further comprises a pressure monitoring port.

6. The apparatus of claim 2 wherein the controller further comprises:
a processor for selectively or continuously sampling data concerning operation of the blood treatment unit; and
a storage device for storing the sampled data.

7. The apparatus of claim 6 wherein the controller further comprises a network interface for transmitting the sampled data from the storage device to a remote computer of a health care provider over a wide area network.

8. The apparatus of claim 6 wherein the controller further comprises a removable-media storage device. the sampled data being transferred to an item of removable storage media in the removable-media storage device for later transmission to a remote computer of a health care provider.

9. The apparatus of claim 2 further comprising means for forcing fluid from each reservoir in acyclical manner and wherein the controller controls the forcing means to provide at least first and second periods having different flow patterns for each cycle of each forcing means.

10. A blood pump for providing physiologic flow of blood comprising:
a pump chamber;
means for forcing blood from the pump chamber; and
a controller for controlling said forcing means wherein said controller provides for at least one of a charge and a discharge stroke a multi-phase flow pattern for each cycle of said pump with a portion of the discharge stroke including a reverse flow of blood.

11. A dialysis pump comprising:
an inlet and an outlet; and
pumping means providing simultaneous inlet and outlet displacement flow patterns which are independent of each other wherein the flow pattern of at least one of said inlet and outlet includes a portion wherein the flow is negative to provide backflow of fluid..

12. A pump for use in a medical treatment apparatus comprising:
a first reservoir including a first piston for direct fluid contact capable of operating in a first cycle of filling with fluid anddischarging fluid; and

a second reservoir including a second piston for direct fluid contact capable of operating in a second cycle of filling with fluid anddischarging fluid;
wherein in operation said first and second cycles are out of phase with each other such that said first reservoir may be filling with fluid for at least a portion of the time while said second reservoir is discharging fluid.

13. Apparatus for producing a time-varying flow of a fluid in a medical treatment unit, the apparatus comprising:
first and second non-compliant reservoirs; and
a valve coupled to the first and second reservoirs wherein said valve is operable to cause said first reservoir to fill while said second reservoir is discharged and said first reservoir to discharge while said second reservoir is filled.

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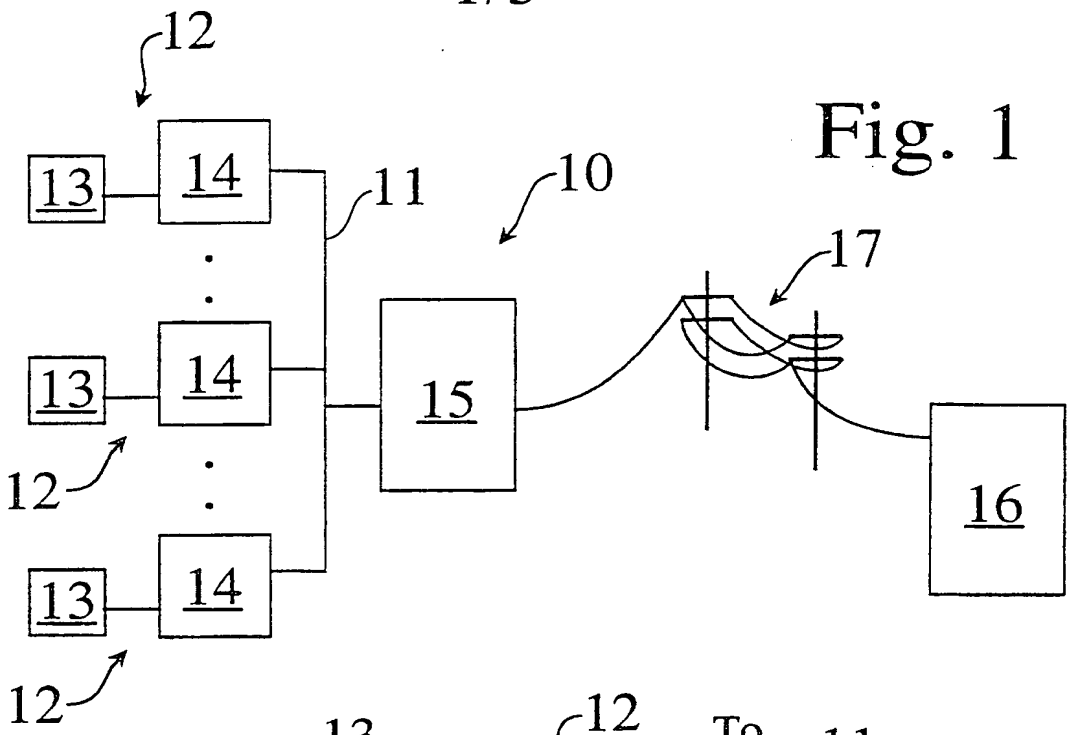



Fig. 1

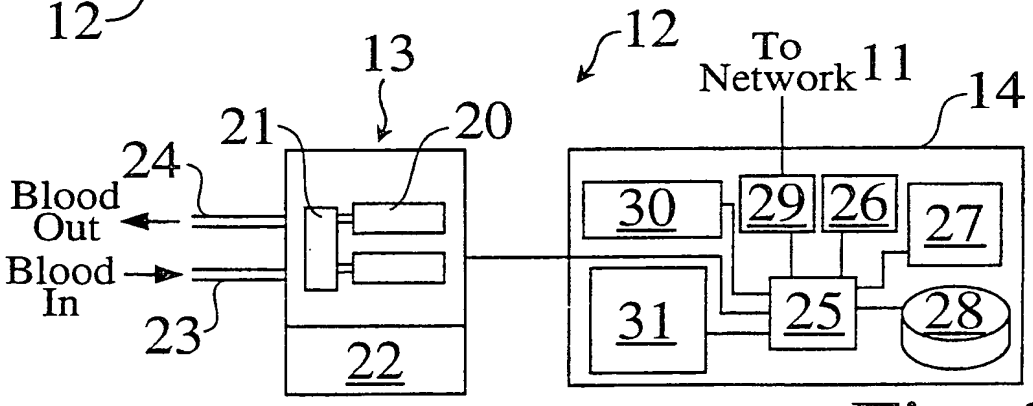



Fig. 2

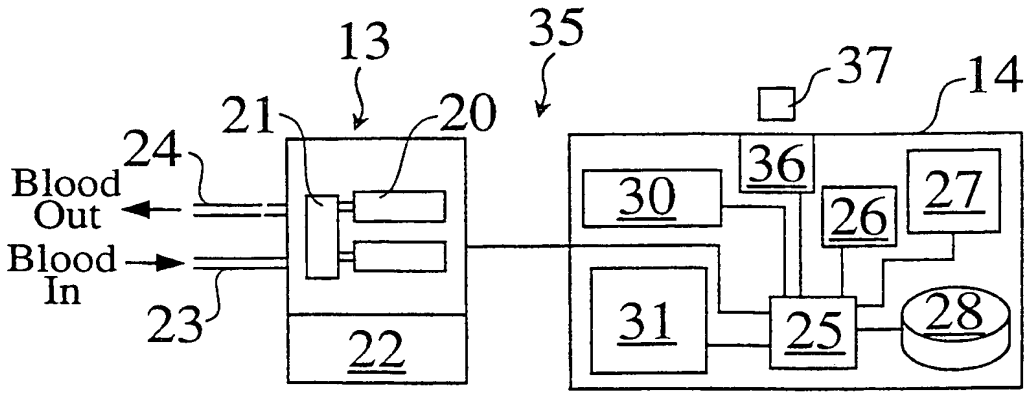
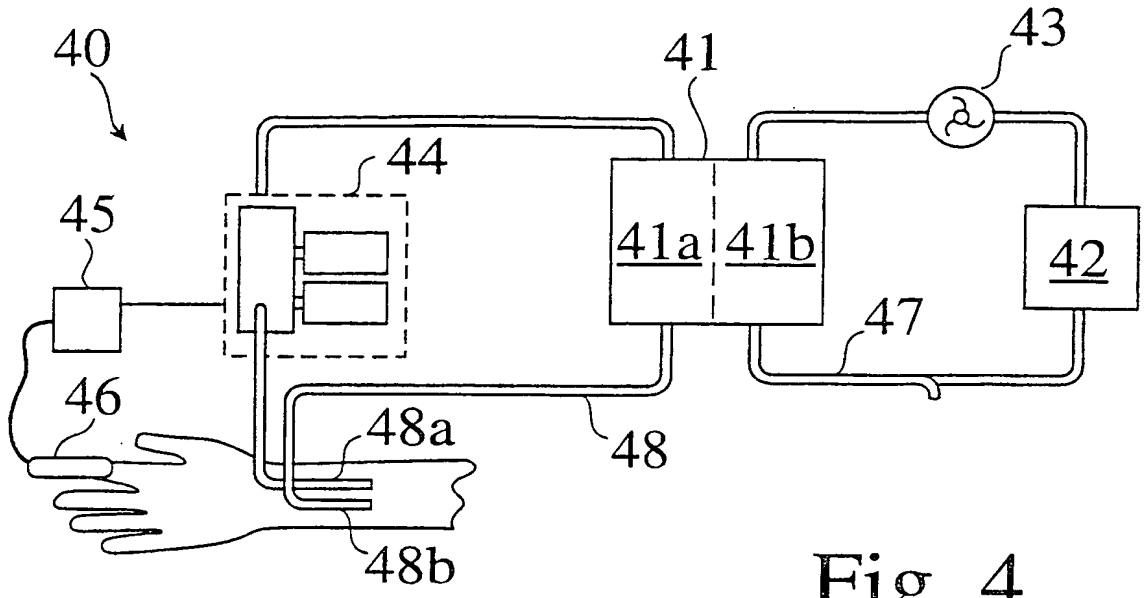



Fig. 3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48a
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48b

Fig. 4

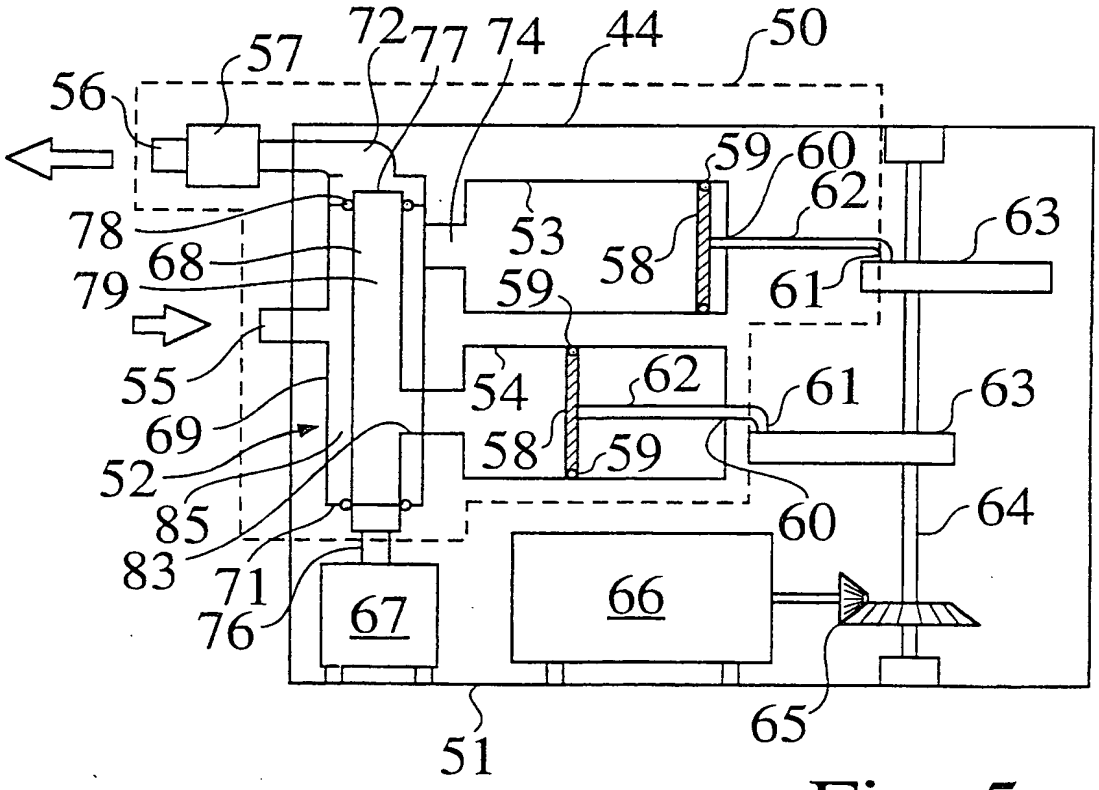
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Fig. 5

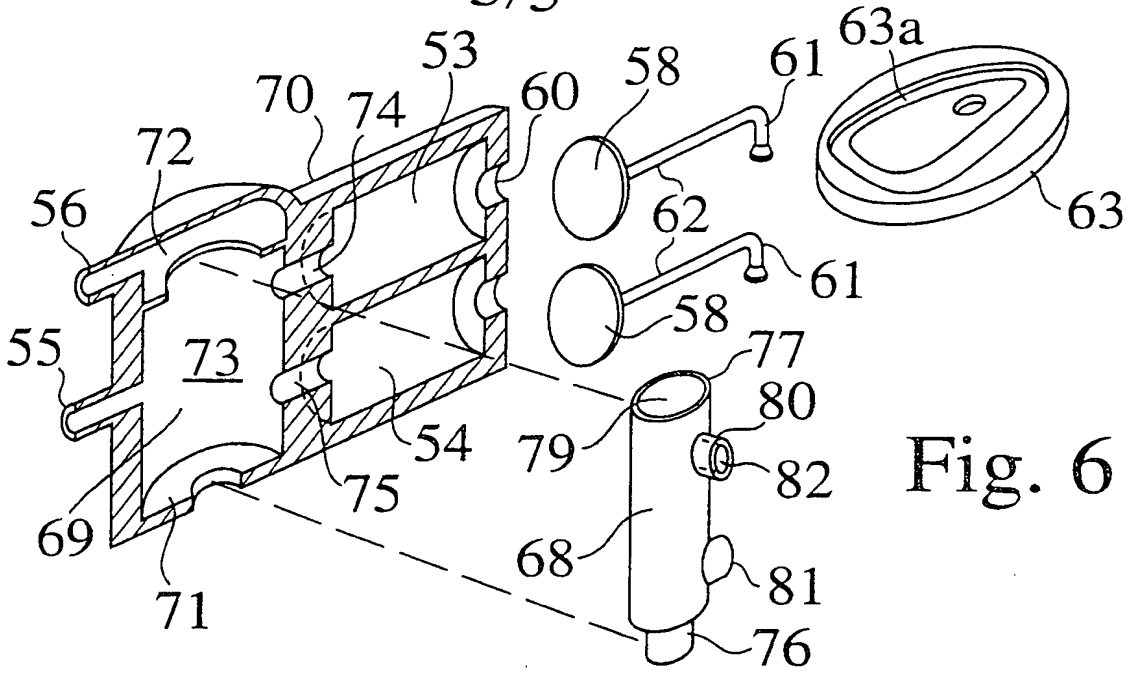


Fig. 6

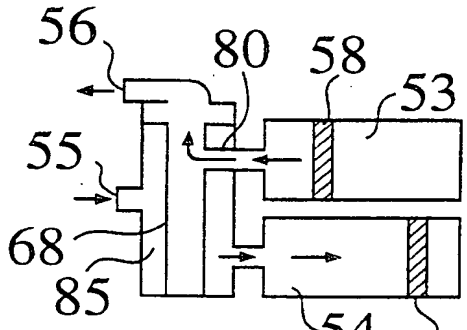


Fig. 7A

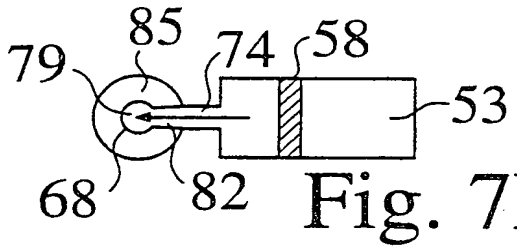


Fig. 7B

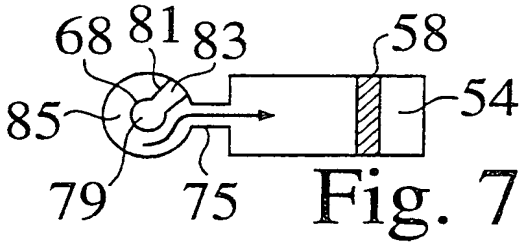


Fig. 7C

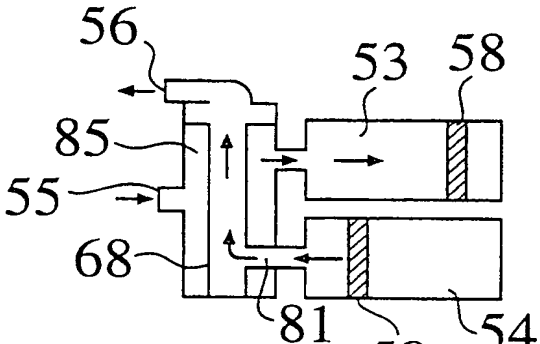


Fig. 8A

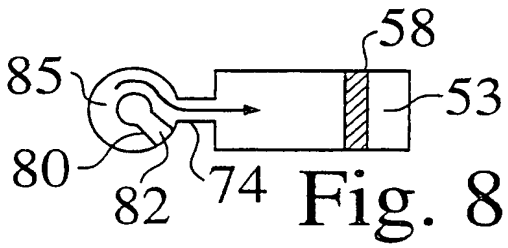


Fig. 8B

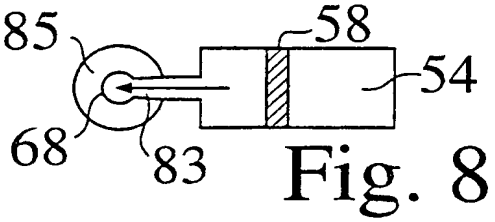


Fig. 8C

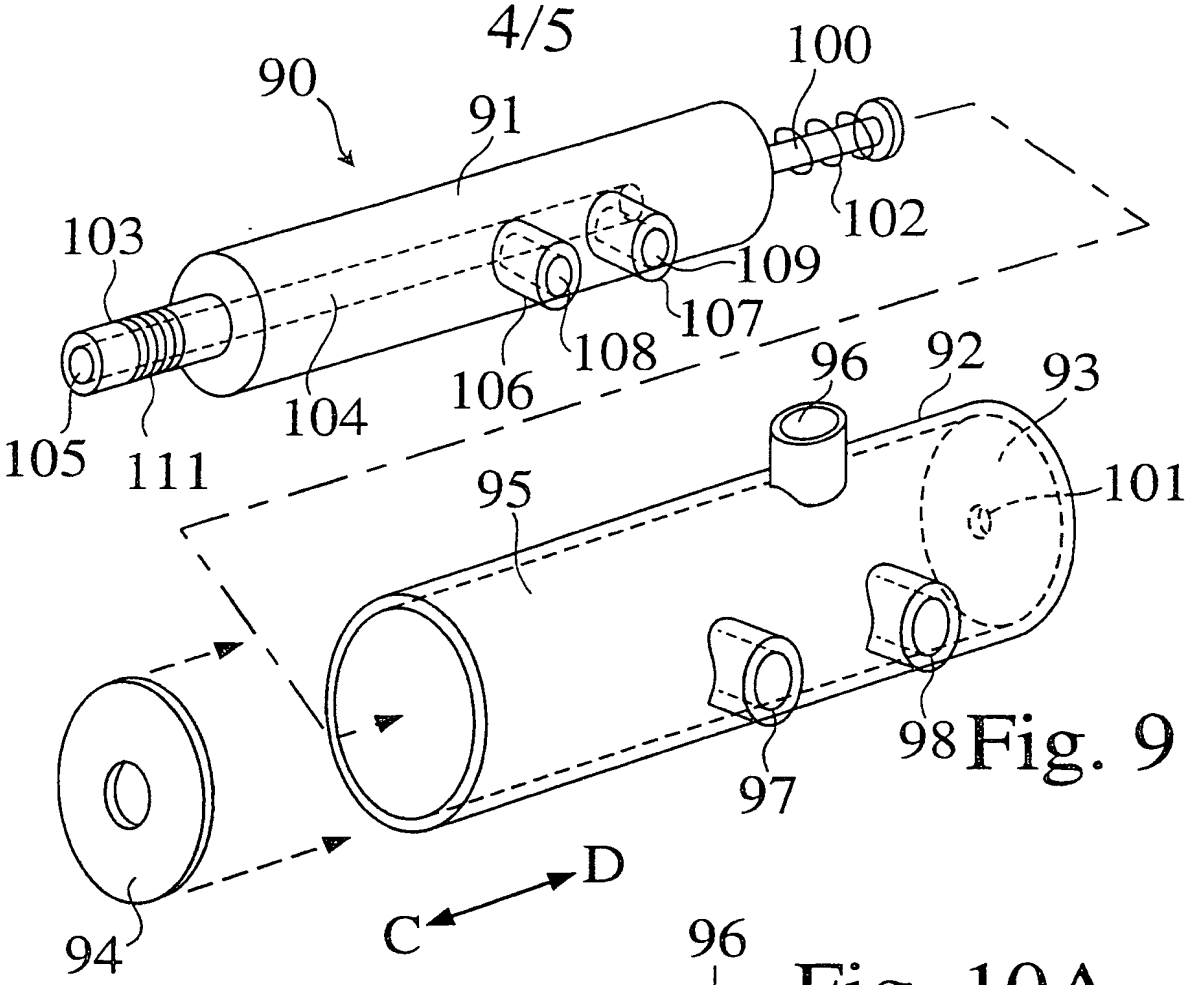


Fig. 9

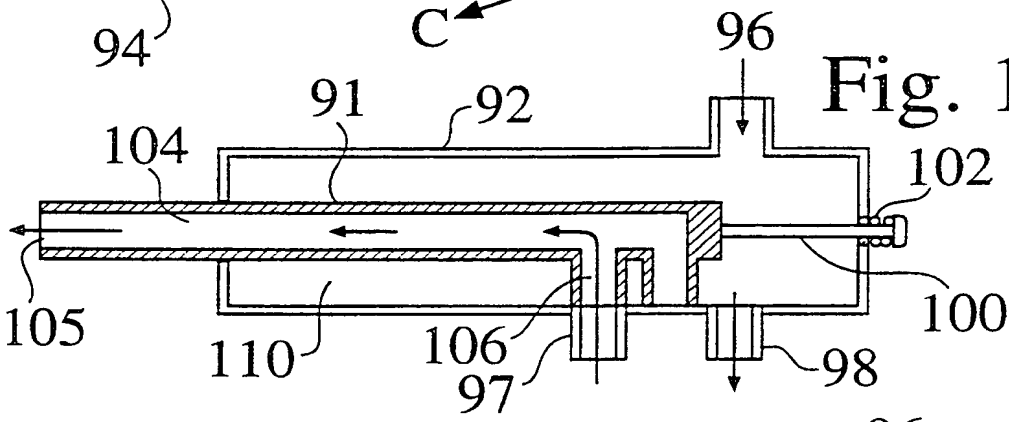


Fig. 10A

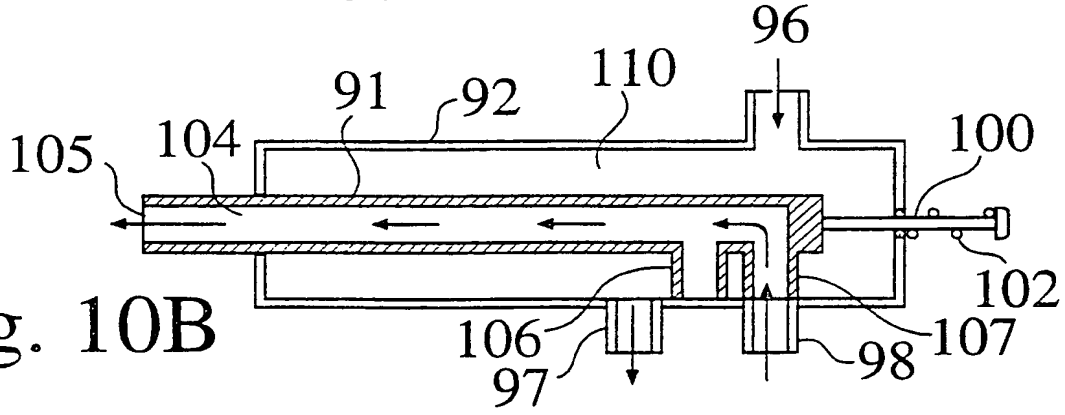


Fig. 10B

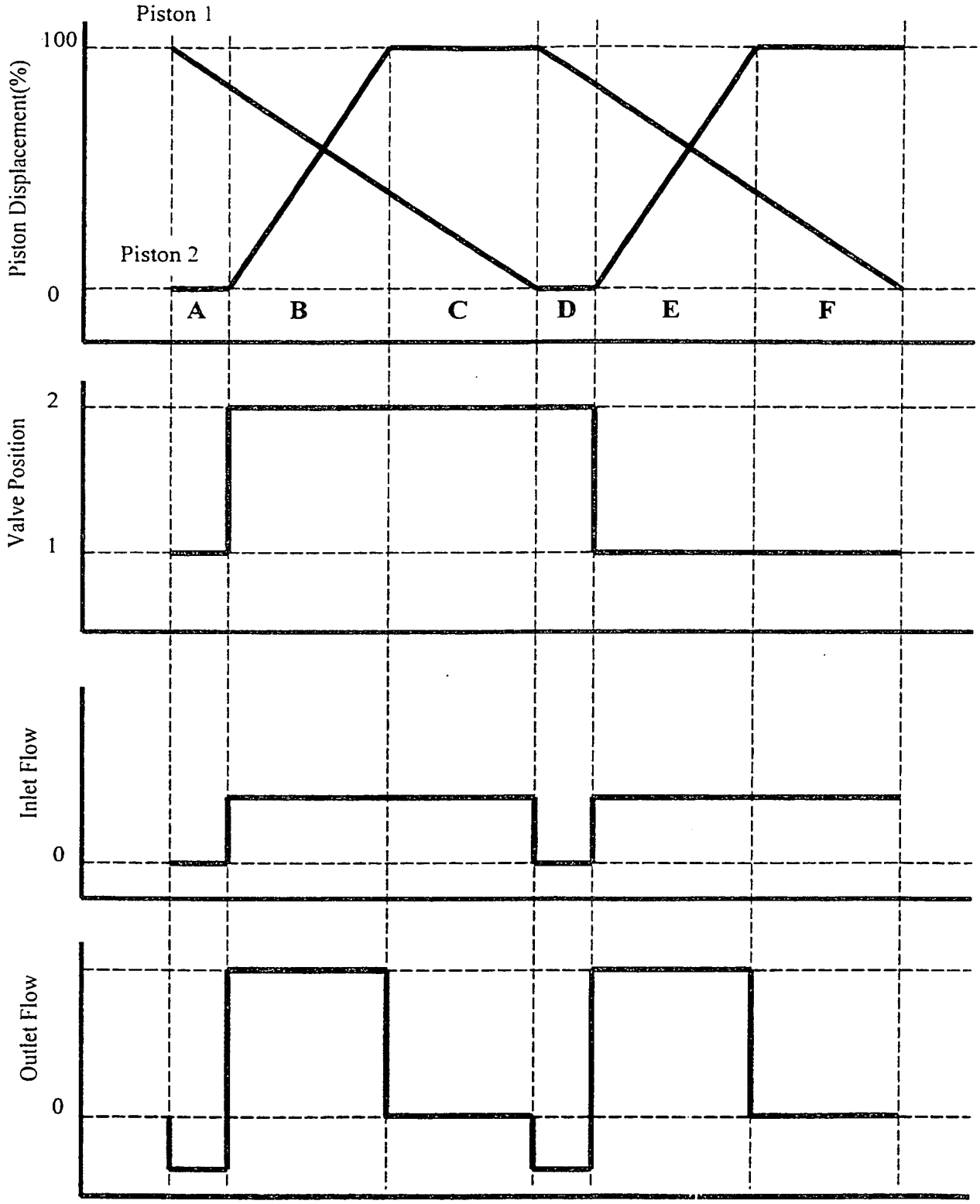
Piston 1
100
Piston Displacement(%)
Piston 2
0
A
B
C
D
E
F
2
Valve Position
1
Inlet Flow
0
Outlet Flow
0

Fig. 11